K103634

510(k) Summary

FEB 2 3 2011

Submission Date:	10 December 2010
Submitter:	Ascom (US), Inc. 598 Airport Boulevard, Suite 300 Morrisville, NC 27560
Submitter and Official Contact:	Mr. Thomas Kroenke Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 +1 (303) 956-4232 tkroenke@speedtomarket.net
Manufacturing Site:	Ascom (US), Inc. 598 Airport Boulevard, Suite 300 Morrisville, NC 27560
Trade Name:	Ascom ClinicalConneX | Cardiomax
Common Name:	Network and Communication Middleware
Classification Name:	System, Network And Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:	*Ascom Model*	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
	Ascom ClinicalConneX | Cardiomax	K062278	Spacelabs Medical, Inc. / Spacelabs Medical Clinical Event Interface (CEI), Model 91847

Device Description:

The Ascom (US), Inc. (Ascom) ClinicalConneX | Cardiomax (Cardiomax) is an on-site messaging integration solution which forwards patient monitor status and alarm information to the user via display devices provided by Ascom or third-party mobile device companies. Users receive interactive, time-critical information from patient monitoring devices directly via their display devices as voice, text, alarms or data. The Ascom Cardiomax allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

The Ascom Cardiomax connects to the information sources through wired ethernet connections which are part of the customer's infrastructure. The Ascom Cardiomax software acquires patient data from patient monitoring devices. The user configures the Ascom Cardiomax to determine which information, including alarm notifications, is delivered to which users. The Ascom Cardiomax then formats the data for wireless delivery to the display devices.

All messaging activities are recorded in the Ascom Communications Server providing real-time activity logging for audit trail records and reporting. The Ascom Cardiomax hardware consists of small, embedded network appliances, and application-specific software. The Ascom Cardiomax delivers near real-time text messaging alerts and information to text-capable display devices.

Ascom provides a wireless communications system platform on which the Ascom Cardiomax may operate: DECT (Digital Enhanced Cordless Telecommunications) technology. The Ascom Cardiomax, combined with an Ascom wireless communication system, is part of an Ascom end-to-end solution designed to provide all the components necessary to optimize work flow, including display devices, gateways and device management.

Intended Use:

The intended use of the Ascom ClinicalConneX | Cardiomax (Cardiomax) is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s).

For medical, near real time alarms, the Ascom Cardiomax is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. Ascom Cardiomax does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audio and/or vibrating mechanism upon receipt of the alert.

The Ascom Cardiomax is intended for use as a secondary alarm. It does not replace the primary alarm function on the monitor.

Technology Comparison:	The Ascom Cardiomax employs the same or similar technological characteristics as the predicate device.
Performance Testing:	
Sterilization and Shelf-Life	The Ascom Cardiomax is not provided sterile and is not intended to be sterilized by the user. Additionally, the Ascom Cardiomax does not have a shelf-life. Therefore, this section is not applicable.
Biocompatibility	The Ascom Cardiomax does not directly or indirectly contact the patient. Therefore, this section is not applicable.
Software Testing	Software for the Ascom Cardiomax was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Ascom Cardiomax complies with its predetermined specifications.
Electrical Safety	The Ascom Cardiomax was tested for electrical safety in accordance with applicable Standards. Test results indicated that the Ascom Cardiomax complies with its predetermined specifications and with the applicable standards.
Electromagnetic Compatibility Testing	The Ascom Cardiomax was tested for EMC in accordance with applicable Standards. Test results indicated that the Ascom Cardiomax complies with its predetermined specifications and with the applicable standards.
Performance Testing – Bench	The Ascom Cardiomax was tested for performance in accordance with predetermined specifications and applicable Standards. Test results indicated that the Ascom Cardiomax complies with its predetermined specifications.
Conclusion	Based upon a comparison with predicate devices and testing results, the Ascom Cardiomax is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 21 2011

Ascom, Inc.
c/o Mr. Thomas Kroenke
Speed to Market, Inc.
PO Box 3018
Nederland, CO 80466

Re: K103634
Trade Name: Ascom ClinicalConneX/Cardiomax
Regulation Number: 21 CFR 870.2300
Regulation Name: Network and Communication, Physiological Monitors Systems
Regulatory Class: Class II (two)
Product Code: MSX
Dated: December 10, 2010
Received: December 13, 2010

Dear Mr. Kroenke:

This letter corrects our substantially equivalent letter of February 23, 2011.

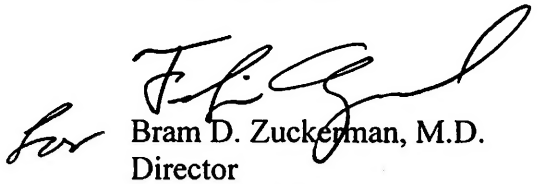
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103634

Device Name: Ascom ClinicalConneX | Cardiomax

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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